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VIA CM-ECF

The Honorable Leonard P. Stark
United States District Court
For the District of Delaware
844 North King Street
Wilmington, DE 19801

Public Version Filed: December 19, 2019

Re: *H. Lundbeck A/S v. Apotex Inc. et al.*, C.A. No. 18-088 (LPS) (consolidated)

Dear Chief Judge Stark:

I am writing on behalf of Defendants Sandoz Inc. (“Sandoz”) and Lek Pharmaceutical d.d. (“Lek”) (collectively, “Sandoz Defendants”) to inform Your Honor of new information related to the Sandoz Defendants’ pending motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) and to Dismiss for Lack of Subject Matter Jurisdiction under Fed. R. Civ. P. 12(b)(1) (“Sandoz Motion”) (D.I. 415), which is set for hearing on Wednesday, December 18, 2019 (D.I. 551).

On December 4, 2019, Sandoz submitted the attached revised patent certification to the U.S. Food & Drug Administration for its Abbreviated New Drug Application No. 210993, which is at issue in the above-captioned suit. (Ex. A.) With the December 4 certification, Sandoz has converted its prior statements under 21 U.S.C. § 355(j)(2)(A)(viii) (“section viii statement”) for U.S. Patent Nos. 9,125,908, 9,125,909, and 9,125,910 to certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“Paragraph III certification”).

Respectfully,

/s/ Dominick Gattuso

Dominick T. Gattuso (#3630)

Enclosure

cc: Clerk of the Court (via hand delivery)
Plaintiffs’ Counsel of Record (via electronic mail)